

Remarks

Status of the Drawings

Figure 20G was objected to under Rule 84 for allegedly having multiple parts without projection lines indicating that the drawing is an expanded view and that the parts thereof are all still parts of the same device. Figure 20G has been amended to include projection lines. No new matter has been added by this amendment. Applicants respectfully request entry of this amendment.

Status of the Claims

Claims 11-13, 30-33, 35, 39, 56, 60, 61, 64, 67-69, 71, 72, and 74-80 were rejected in the May 18, 2007 Office Action. Upon entry of the above amendments, claims 12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78, and 80 will remain pending in the present application, claims 11, 13, 33, 56, 60, 67, and 79 having been cancelled in the above amendments. New dependent claims 102-114 have been added.

Claims 30 and 61 are the independent claims that are pending in the present application.

Applicants maintain that claims 11, 13, 33, 56, 60, 67, and 79 are patentable over the rejections. However, claims 11, 13, 33, 56, 60, 67, and 79 have been cancelled to advance prosecution of the remaining claims. The cancellation of claims 11, 13, 33, 56, 60, 67, and 79 renders rejections related to those claims moot. Therefore those rejections will not be addressed further.

Claim 74 has been amended from “comprises” to “further comprises” in response to the objection in the May 18, 2007 Office Action. Claims 12, 35, 39, 68-69, 71-72, 74-78 and 80 have been amended to change their dependency. Claim 35 has also been amended to correct a typographical error. The amendments to claim 61 and new claims 102-106 are supported throughout the specification. For example, at page 18, lines 10-15 the specification states:

In a further embodiment according to this invention, assembled cortical bone blocks, or cortical cancellous bone blocks, or bone blocks comprised of a combination of cortical bone, cortico-

cancellous bone, cancellous bone, and /or synthetic materials as described elsewhere herein, are assembled in combination with wedged or pinned **soft tissue, such as tendon, ligament, skin, collagen sheets, or the like** to create grafts similar to naturally occurring tissue sites, such as the bone-tendon interface found at the patella.

(Emphasis added). New claims 107-108 are supported throughout the specification, for example, at page 15, line 29 to page 16, line 1, and by original claims 17 and 32. New claims 109-110 are supported throughout the specification, for example, at page 14, line 29 to page 15, line 1 and page 21, line 22. New claims 111-112 are supported throughout the specification, for example, at page 15, line 22 and by Figures 8-18. New claims 113-114 are supported throughout the specification, for example, by Figures 28-29. No new matter has been added by these amendments. Applicants respectfully request entry of these amendments.

The Pending Claims Are Not Obvious Based On EP 0517030 (Siebels) and U.S. Pat. 5,989,289 (Coates)

Claims 12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78, 80 and 102-114 are currently pending. Claims 12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78 and 80 currently stand rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. No. 5,989,289 (Coates). Applicants respectfully disagree with the Patent Office's rejection as discussed below.

Claim 30 recites an assembled graft implant comprising two or more individual segments fastened together with at least one pin machined from cortical bone. At least one segment is a demineralized segment of allograft bone, and at least one segment is a mineralized segment of allograft cortical bone. Each segment has a hole drilled therein for receiving and frictionally engaging said at least one pin.

Applicants submit that neither Siebels nor Coates can render claim 30 unpatentable because neither Siebels nor Coates discloses or suggests an assembled graft implant where a demineralized segment of allograft bone is fastened together with a mineralized segment of allograft cortical bone. Also neither reference teaches or suggests

an assembled bone implant where a demineralized segment has a hole drilled therein for receiving and frictionally engaging said at least one pin.

The only materials specifically discussed in Siebels for making disks and/or pins are fiber-reinforced plastic and carbon-fiber reinforced plastic. The May 18, 2007 Office Action acknowledges this fact, stating “Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6).” (May 18, 2007 Office Action, p. 4). Nowhere does Siebels disclose or suggest use of any bone material.

Coates does not disclose or suggest a demineralized bone segment fastened together with a mineralized bone segment, nor an assembled graft implant where demineralized and mineralized bone segments are fastened together with at least one pin machined from cortical bone. The only discussion of demineralized bone in Coates is at column 6, lines 23-38.

An osteogenic material can be applied to the spacers of this invention by **packing the chamber** 130 with an osteogenic material 148 as shown in FIG. 4, by **impregnating the graft** with a solution including an osteogenic composition or by both methods combined. ... Any suitable osteogenic material or composition is contemplated, including autograft, allograft, xenograft, **demineralized bone**, synthetic and natural bone graft substitutes, such as bioceramics and polymers, and osteoinductive factors.

(Coates Col. 6, lines 23-38)(emphasis added). Coates does not disclose a demineralized bone segment that is fastened together with a mineralized bone segment by at least one pin. Coates also does not teach or suggest a hole drilled in a demineralized segment for receiving and frictionally engaging a pin. In fact, it is unlikely that an osteogenic material packed into a chamber (such as a sponge or foldable strips or sheets) or impregnated into a graft (such as by applying a liquid osteogenic material to the graft) as discussed in Coates (see col. 7, lines 44-47 and col. 8, lines 8-18) would be effective in frictionally engaging a pin.

The May 18, 2007 Office Action contended that a person skilled in the art would have modified the implant of Siebels by replacing the fiber-reinforced plastic with

cortical bone, and further that the cortical bone used in such a replacement could include a demineralized segment and a mineralized segment. The Office Action stated:

Regarding claim 30, the spaces of Coates can have osteogenic material of demineralized bone and /or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Therefore, all the pieces could be called a mineralized segment or a demineralized segment since each piece would contain at some (sic) of each material.

(Office Action, page 5). In other words, the Office Action contends that a person skilled in the art would have found it obvious to replace each disk or pin in Siebels with a complete spacer described by Coates. The Office Action is incorrect. There is no reason to believe that the fiber-reinforced plastic disks or pins could be replaced with a spacer having an osteogenic material packed in its chamber, or that a person skilled in the art would have a reason for doing so. Moreover, the Office Action fails to identify a reason why such an implant would include a demineralized bone segment having a hole drilled therein for receiving and frictionally engaging said at least one pin. Thus, Siebels and Coates do not render claim 30 unpatentable for obviousness.

Claims 12, 31, 32, 107-109 and 111-112 depend from claim 30. Since claims 12, 31, 32, 107-109 and 111-112 incorporate all of the limitations of their base independent claim 30, applicants submit that the allowability of claim 30 renders claims 12, 31, 32, 107-109 and 111-112 allowable as well.

Claim 61 recites an assembled implantable bone graft suitable for use in humans. The graft comprises a first machined segment of allograft bone pinned with at least one pin to a second machined segment of allograft bone. The graft also comprises a soft tissue affixed between said first segment and said second segment. Applicants submit that Siebels and Coates do not render claim 61 unpatentable because both Siebels and Coates fail to disclose or suggest a soft tissue affixed between a first bone segment and a second bone segment.

As discussed above, the only materials specifically discussed in Siebels for making disks and/or pins are fiber-reinforced plastic and carbon-fiber reinforced plastic.

Siebels does not disclose or suggest the use of any tissue, particularly soft tissue affixed between a first bone segment and a second bone segment as recited by claim 61.

Coates also fails to disclose or suggest using a soft tissue affixed between a first bone segment and a second bone segment. As discussed above, Coates “avoid[s] the disadvantages of metal implants” by making bone implants. (Coates, Col. 4, lns. 8-16). The May 18, 2007 Office Action specifically notes that “Coates...teaches it was known to make similar spinal implants out of allograft or autograft cortical bone.” (May 18, 2007 Office Action, p. 4). Nowhere does Coates disclose or suggest an assembled implantable bone graft comprising a soft tissue, as recited by claim 61.

The arguments in the May 18, 2007 Office Action that “since bone is inherently flexible to some extent, the middle discs of Siebels as modified by Coates would meet the claim language calling for a flexible tissue” are rendered moot by Applicant’s amendment from “flexible tissue” to “soft tissue.” (May 18, 2007 Office Action, p. 5). Applicants submit that bone does not constitute a “soft tissue” in the context of the present application. Thus, Siebels and Coates cannot render amended claim 61 unpatentable for obviousness.

Claims 35, 39, 64, 68-69, 71-72, 74-78, 80, 102-106, 110 and 113-114 depend from claim 61. Since claims 35, 39, 64, 68-69, 71-72, 74-78, 80, 102-106, 110 and 113-114 incorporate all of the limitations of their base independent claim 61, applicants submit that the allowability of claim 61 renders claims 35, 39, 64, 68-69, 71-72, 74-78, 80, 102-106, 110 and 113-114 allowable as well.

For at least these reasons, the combination of the Siebels and Coates references would not have rendered claims 12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78, 80 and 102-114 obvious to a person skilled in the art at the time that the Applicants’ invention was made.

Conclusion

Although the Office Action makes various statements regarding claims 30-12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78 and 80 and the cited references that are now

moot in light of the above, applicants expressly reserve the right to challenge such statements in the future should the need arise (for example, if such statement(s) become relevant by appearing in a rejection of any current or future claim).

In view of the amendments and arguments provided herein, Applicants believe that all bases for rejecting claims 12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78 and 80 have been overcome. Applicants respectfully submit that claims 12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78, 80 and 102-114 of the instant application are in a condition for allowance. The Examiner is invited to telephone the applicants' undersigned attorney at (312) 775-8213, if any unresolved matters remain.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Account No. 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Respectfully submitted,

Date: November 19, 2007

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